

February 22, 2000

FOR Docket No. 99D-5347

TO The FDA-

Unfortunately your proposed guidelines to defer blood transfusions originating from Xenotransplants is inadequate and will not be sufficient to protect the blood supply in the US.

In order to be 100% sure that Xenotransplants, their close contacts and their health care personnel do not donate blood, we would have to have a computerized registry of the names & locations of all persons so involved. Such a registry besides being an invasion of privacy, would be expensive to support ~~and~~ subject to errors from many sources.

Some Xenograph patients may harbor latent viruses which may not appear for decades. Other Xenograph patients may pass along viruses as easily as a common cold to casual contacts who would have no way of knowing if they were infected or carriers.

With all the problems associated with ensuring a safe adequate blood supply for those in need, we have now blood shortage problems.

Xenotransplantation will shrink the available blood donor pool even further & thus lessen the available blood pool at any given time. Since we are interacting with infectious disease carriers, the contained policy is not acceptable. To maintain and protect the blood supply and the subsequent health of Americans, the FDA has no choice but to ban Xenotransplantation now.

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